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20 **UNITED STATES DISTRICT COURT**

21 **CENTRAL DISTRICT OF CALIFORNIA**

22 SANDOZ INC.,

23 Plaintiff,

24 v.

25 AMGEN INC.,

26 Defendant.

Case No. 2:22-cv-05326-RGK-MAR

**STATEMENT OF UNCONTROVERTED
FACTS OF AND CONCLUSIONS OF
LAW IN SUPPORT OF AMGEN INC.'S
MOTION FOR SUMMARY JUDGMENT
[L.R. 56-1]**

Date: Monday, June 26, 2023

Time: 9:00 a.m.

Place: Courtroom 850

In support of its motion for summary judgment, Defendant Amgen Inc. (“Amgen” or “Defendant”), respectfully submits the following Statement of Uncontroverted Facts and Conclusions of Law pursuant to Local Rule 56-1.

UNCONTROVERTED FACTS

<u>Uncontroverted Fact</u>	<u>Supporting Evidence</u>
<u>Uncontroverted Facts Relating to the Absence of Evidence of Injury to Sandoz</u>	
1. There is an absence of evidence of any identified patient who purchased and took, prescriber who prescribed, or payer who reimbursed Neulasta® Onpro® in lieu of Ziextenzo® as a result of the Amgen promotional materials at issue in this lawsuit.	Akro. Decl. Exh. N at 229-33 [Delo Tr. 207:19-211:7]; Exh. G at 129-30, 131-36, 138-40 [Delo 30(b)(6) Tr. 254:4-255:3, 256:8-261:6, 266:5-268:16]; Exh. V at 322-23, 327, 328 [Li 30(b)(6) Tr. 207:4-208:4, 212:9-17, 213:6-14].
2. The challenged Amgen promotional materials do not identify either Sandoz or Ziextenzo® by name.	Akro. Decl. Exh. L at 182 [RFAs 77-78].
3. At all times relevant to this lawsuit, there have been Neulasta® and at least three (and as many as six) FDA-approved pegfilgrastim biosimilars.	Akro. Decl. Exh. D at 83-85 [RFAs 13, 14, 19-21].
<u>Uncontroverted Facts Relating to Other Failures of Proof Pertinent to Injunctive Relief</u>	
4. The Amgen promotional materials based on the study described in Paragraphs 51-91 of Sandoz’s Complaint (described therein at the “2019 Amgen	Complaint (Dkt. No. 1) ¶ 90 (alleging Amgen’s use of promotional materials based on the 2019 Amgen Study “From 2020 through 2021”); Akro. Decl. Exh. B

Study”) have not been used in commercial advertising or promotion since 2021.	at 50-51 [Campbell Tr. 160:20-161:1].
5. Sandoz has not conducted any survey relating to the challenged Amgen promotional materials.	Akro. Decl. ¶ 2.

CONCLUSIONS OF LAW

<u>Conclusion of Law</u>	<u>Supporting Authority</u>
1. Summary judgment is appropriate where “there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law.”	Fed. R. Civ. P. 56(a); <i>Celotex Corp. v. Catrett</i> , 477 U.S. 317, 322 (1986).
2. When the plaintiff bears the burden of proof on its claims, the defendant may prove the “absence of a genuine issue of material fact” by “pointing out to the district court . . . that there is an absence of evidence to support the [plaintiff’s] case.”	<i>Celotex</i> , 477 U.S. at 325.
3. In a “suit for damages under” the Lanham Act, “actual evidence of some injury resulting from the deception is an essential element of the plaintiff’s case.”	<i>Harper House, Inc. v. Thomas Nelson, Inc.</i> , 889 F.2d 197, 210 (9th Cir. 1989); <i>see also Lexmark Int’l, Inc. v. Static Control Components, Inc.</i> , 572 U.S. 118, 140 (2014); <i>Quidel Corp. v. Siemens Med. Solutions USA, Inc.</i> , 2021 WL 4622504, at *1 n.1, 2-3 (9th Cir. Oct. 7,

	<p>2021); <i>Grasshopper House, LLC v. Clean & Sober Media, LLC</i>, 2021 WL 3702243, at *1-2 (9th Cir. Aug. 20, 2021); <i>VBS Distrib., Inc. v. Nutrivita Labs., Inc.</i>, 811 F. App'x 1005, 1007 (9th Cir. 2020); <i>Verisign v. XYZ.COM LLC</i>, 848 F.3d 292, 299 (4th Cir. 2017); <i>BMMG, Inc. v. Am. Telecasat Corp.</i>, 42 F.3d 1398 (Table), at *1 (9th Cir. 1994); <i>Telecredit Serv. Corp. v. Elec. Trans. Corp.</i>, 974 F.2d 1343 (Table), at *2 (9th Cir. 1992); <i>Quidel Corp. v. Siemens Med. Sols. USA, Inc.</i>, 2020 WL 4747724, at *7-11 (S.D. Cal. Aug. 17, 2020).</p>
<p>4. Under the Lanham Act, disgorgement of the defendant's profits is inappropriate without "proof of past injury or causation," except for "in false comparative advertising cases" or when the "defendant associates its product with [the] plaintiff's noncompetitive product to appropriate good will or brand value."</p>	<p><i>TrafficSchool.com, Inc. v. Edriver Inc.</i>, 653 F.3d 820, 831 (9th Cir. 2011); <i>see also Quidel</i>, 2021 WL 4622504, at *2; <i>Distrib. LLC v. IronMag Labs, LLC</i>, 2018 WL 6264986, at *2 (C.D. Cal. Nov. 16, 2018); <i>Biocell Tech. LLC v. Arthro-7</i>, 2013 WL 12063914, at *11-12 (C.D. Cal. May 22, 2013).</p>
<p>5. Under California's False Advertising Law and Unfair Competition Law, a plaintiff must prove that its alleged "economic injury was the result of, i.e., caused by, the unfair business practice or</p>	<p><i>Kwikset Corp. v. Super. Ct.</i>, 51 Cal. 4th 310, 322 (2011); <i>see also Patten v. Vertical Fitness Grp.</i>, 847 F.3d 1037, 1049 (9th Cir. 2017); <i>Quidel</i>, 2020 WL 4747724, at *4, 12.</p>

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	<p>false advertising.”</p> <p>6. A Lanham Act plaintiff is not entitled to a presumption of injury when the defendant’s “advertising does not directly compare defendant’s and plaintiff’s products” or “numerous competitors participate in a market.”</p>	<p><i>Harper House</i>, 889 F.2d at 209 n.8; <i>see also TrafficSchool.com</i>, 653 F.3d at 826; <i>Quidel</i>, 2021 WL 4622504, at *2; <i>Quidel</i>, 2020 WL 4747724, at *11; <i>Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.</i>, 2011 WL 4852472, at *3 (C.D. Cal. Oct. 12, 2011); <i>Out of the Box Enters., LLC v. El Paseo Jewelry Exch., Inc.</i>, 2012 WL 12893690, at *13 (C.D. Cal. May 11, 2012); <i>Falcon Stainless, Inc. v. Rino Cos.</i>, 2011 WL 13130703, at *15 (C.D. Cal. Oct. 21, 2011); <i>Munchkin, Inc. v. Playtex Prods., LLC</i>, 2012 WL 12886205, at *5 (C.D. Cal. Oct. 4, 2012); <i>CKE Rest. v. Jack in the Box, Inc.</i>, 494 F. Supp. 2d 1139, 1146 (C.D. Cal. 2007).</p>
19 20 21 22 23 24 25 26 27 28	<p>7. A false advertising plaintiff cannot receive a permanent injunction without proving that it faces a “likelihood of future injury” proximately caused by the defendant’s advertising.</p>	<p><i>Lexmark</i>, 572 U.S. at 127, 135; <i>City of Oakland v. Wells Fargo & Co.</i>, 14 F.4th 1030, 1042 (9th Cir. 2021); <i>Quidel</i>, 2020 WL 4747724, at *11; <i>Williams & Cochrane, LLP v. Rosette</i>, 2022 WL 4544711, at *22-23 (S.D. Cal. Sept. 27, 2022); <i>Nutrition Distrib. LLC v. Lecheek Nutrition, Inc.</i>, 2015 WL 12659907, at *7 (C.D. Cal. June 5, 2015); <i>Allergan USA</i></p>

Inc. v. Imprimis Pharm., Inc., 2019 WL 3029114, at *3 (C.D. Cal. July 11, 2019); *McCrary v. Elations Co.*, 2014 WL 12561600, at *6-7 (C.D. Cal. Dec. 8, 2014).

Dated: May 24, 2023

KING & SPALDING LLP

By: /s/Joseph N. Akrotirianakis
JOSEPH N. AKROTIRIANAKIS

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